REMARKS

Reconsideration of this application as amended is respectfully requested. Applicants are filing herewith a Notice of Appeal. However, if the Examiner has any proposed further amendment to the two pending claims, Applicants would greatly appreciate a telephonic interview to hasten disposition of this case prior to the appeal process. Examiner is therefore encouraged to contact Applicants' attorney at the telephone number listed below. Also submitted herewith is a Petition for a Two-Month Extension of Time.

Claims 1 and 2 are pending in this application. Claims 1 and 2 have been amended to better clarify the nature of the invention. Support for the amendment regarding the specification of mammary cells can be found on page 3 the last two sentences as well as the first 3 lines of page 4 of the specification and also on page 15, the last 5 lines. Also, see figure 4 for support.

It is well known in the art that, due to the degeneracy of the genetic code, slightly different nucleotide sequences can encode the same polypeptide.

No new matter has been added as a result of this amendment.

Claim objections

Claim 1 is objected to because of the following informalities: in the newly added portion of the claim the word "amound" is a typographical error. Applicant has corrected

this error by substituting the word "amount". Thus, this objection to claim 1 should be withdrawn.

Claim Rejections Under 35 U.S.C. §112, ¶1

The Examiner has rejected claims 1 and 2 under 35 U.S.C. §112, ¶1 alleging that the claimed subject matter is not described in the specification in such a way as to enable one skilled in the art to practice the invention. The Examiner bases this rejection on five grounds which are as follows:

First, the Examiner asserts that the scope of the claims include the detection of tumor progression for any type of cancer. Applicant has amended the claims to clarify that the processes claimed are solely for human mammary tumors. Thus, this rejection should be withdrawn.

Secondly, the Examiner rejects the claims based on the language of step (iii) stating that the nucleic acids claimed can cover a multitude of sequences due to the language "hybrizes to SEQ ID NO:1 under stringent conditions". Applicant has amended the claims to specify that nucleic acids other than those of SEQ ID NO:1 or a complement thereof must be "though not identical to those nucleic acids of (i) and (ii), due to the degeneracy of the genetic code encode a polypeptide having the amino acid sequence of the polypeptide encoded by SEQ ID NO:1". Thus, this rejection should be withdrawn.

Thirdly, the Examiner rejects claims 1 and 2 asserting that Figure 4 shows that only four out of eleven mammary carcinoma cell lines scored positive for the

upregulated expression of PKW, as measured in an RT-PCR assay (Example 9). Thus, she concludes that the processes claimed are not predictive of mammary cancer. However, Applicants are not claiming a diagnostic method for detecting all mammary cancers, but rather a process for determining whether cells or tissues may have "tumor progression potential". Many medical tests do not detect all pathological conditions but are utilized as screens for further tests, for example in the case of a mammogram. These tests are still worthwhile to patients especially if used in conjunction with further tests. Surely patients would benefit from a simple cell-based screen which might alert them as to the potential for the possibility of developing certain types of mammary carcinomas.

Fourth, the Examiner rejects the claims on the basis that cell lines are not as predictive of cancer as compared to utilizing primary tumor tissue to screen for malignancies. Applicant is submitting herewith a publication in a Supplemental Information Disclosure Statement, "Schwirzke, M; Schiemann, S.; Gnirke AU and Weidle AU: Anticancer Res. 19:1801-1814, 1999". This publication supports the reliability of Applicants' in vitro cell line experiments showing a correlation with corresponding behavior in primary tumor tissue for multiple mammary tumors. Specifically, this publication demonstrates that several genes, originally found by in vitro experiments in cell culture were later shown to have the corresponding functional role in human breast cancer. See page 1803, b, "In rodent systems a gene and its corresponding gene product have been identified to be up-regulated in metastatic mammary carcinoma *cell lines* as compared to their non-metastasizing equivalents ...", (emphasis added) See also page 1804, c; as well as pages 1805-06, 3a.

In addition, see Applicants' arguments in regard to point 3 discussed above. Specifically, applicant is not claiming a diagnostic tool, but rather a screen for "tumor progression potential".

Finally, the Examiner rejects claims 1 and 2 based on the assertion that the claims as written encompass using a variety of variants of SEQ ID NO:1 including fragments of SEQ ID NO:1 and sequences which differ form SEQ ID NO:1 as probes for PKW. Applicants have amended the claims to specify that the sequences claimed be SEQ ID NO:1, complements thereof, or sequences "though not identical to nucleotide SEQ ID NO:1 encode the same polypeptide as encoded by SEQ ID NO:1." Thus this rejection to the claims should be withdrawn.

A Petition for a Two-Month Extension of Time is being filed with this Amendment. If any additional fees are deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,

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